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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF (PATENT L.R. 4-5(a))

Markman Hearing
Date: June 25, 2008
Time: To Be Set
Room: Courtroom 6, 4th Floor
Judge: Hon. Ronald M. Whyte

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STATUTES

Pursuant to the Stipulated Scheduling Order, Plaintiffs Hologic, Inc., Cytyc Corporation, and Hologic L.P. (collectively, "Hologic") respectfully submit this Brief addressing the construction of disputed terms, phrases and clauses in the asserted claims of U.S. Patent Nos. 5,913,813 (the "'813 patent"), 6,413,204 (the "'204 patent"), and 6,482,142 (the "'142 patent") (attached hereto as Exhibits A, B, and C, respectively, to the Declaration of Katharine L. Altemus In Support of Plaintiffs' Opening Claim Construction Brief, "Altemus Decl.")[1]. Hologic currently asserts claims 11 and 12 of the '813 patent, claims 4 and 17 of the '204 patent, and claims 1, 6, and 8 of the '142 patent against Defendant SenoRx, Inc. ("SenoRx").

I. PRELIMINARY STATEMENT

Dramatic differences mark the parties' approach to claim construction. Hologic proposes constructions that are straightforward. In many cases, Hologic simply applies the plain meaning of the claim terms as apparent to one of ordinary skill in the art informed by the intrinsic evidence (*i.e.*, the specification and prosecution history). *Accord Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-15 (Fed. Cir. 2005) (en banc), *cert. denied,* 126 S. Ct. 1332 (2006). In contrast, SenoRx urges this Court, without support from or contrary to intrinsic evidence, to restrict the plain meaning of the patent claims. In most cases, SenoRx asks this Court to rewrite the claims to narrow their scope to less than what the inventors actually invented and claimed. SenoRx also requests that the Court limit the claim terms to exemplary embodiments in the specification—or, in some cases—urges constructions that would exclude preferred embodiments. Each of these approaches is erroneous under modern claim construction jurisprudence. SenoRx's strained interpretations of the disputed terms should be rejected.

II. BACKGROUND

A. THE TECHNOLOGY

All three patents-in-suit are related. The '813 patent is the parent. The '204 and '142 patents are continuations-in-part of the '813 patent. Rather than repeat an explanation of the technology of the patents-in-suit with which the Court is well familiar, and in the interest of brevity, Hologic refers the

[1] Unless otherwise noted, all cited exhibits are exhibits attached to the Altemus Decl.

Court to synopses of the technology at issue contained within multiple previous filings with, and orders from this Court, as well as to specific discussions of each patent-in-suit, *infra*. Ex. D at 2-3; Ex. E at 2; Ex. F at 2-3; Ex. G at 4, 6-7.

B. THE EXPERTS

To demonstrate how one skilled in the art[2] would construe the disputed claim terms, Hologic provides the testimony of Dr. Lynn J. Verhey. Dr. Verhey is a well-recognized and independent expert in methods of delivering radiation to cancer patients, and unquestionably qualified to provide opinions as one skilled in the relevant art. He has provided testimony to this Court in the past. His credentials are summarized within the Declaration of Lynn J. Verhey, Ph.D. ("Verhey Decl."), attached as Exhibit H.

III. APPLICABLE LAW

Claim construction begins with the words of the claims themselves, which define the subject matter that the inventors intended to claim. *See Phillips*, 415 F.3d at 1313 ("The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation."). The words of the claims are not interpreted in a vacuum: they must be read in light of other words in the claim, the patent specification, and the prosecution history (*i.e.*, the intrinsic evidence). *See MedRad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005). Importantly, "[a]bsent some particular reason to do otherwise, the claim terms must be interpreted as would one of ordinary skill in the art . . . and in light of the particular patent in suit." *Id.*; *see also Phillips*, 415 F.3d at 1313.

Contextual language—either in the same claim, or in other claims—may be a key to determining what the inventors intended in their use of certain claim terms; and, in any event, should not be ignored. *See Hockerson-Halberstadt, inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999) ("Proper claim construction…demands interpretation of the entire claim in context, not a single element in isolation."). At least as important, the specification—of which the claims are a part—"is

[2] *i.e.*, the objective person from whose perspective the intrinsic evidence must be viewed. *Phillips*, 415 F.3d at 1313.

the single best guide to the meaning of the disputed term." *Phillips*, 415 F.3d at 1315. Within the specification, the inventors may "use a term in a manner either more or less expansive than its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims." *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005).

While the specification is critical to understanding what the inventors claimed as their invention, several principles guide its use in understanding the scope of the claims. First, the Federal Circuit has repeatedly warned against improperly importing limitations into the claim. *See, e.g.*, *MBO Labs., Inc. v. Becton Dickinson,* 474 F.3d 1323, 1333 (Fed. Cir. 2007) (stating that importation of limitations into claims is "fraught with 'danger'" (quoting *Phillips*, 415 F.3d at 1323)); *JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005) ("We do not import limitations into claims from examples or embodiments appearing only in a patent's written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment . . . ."). Second, a claim construction that excludes preferred embodiments "is rarely, if ever correct and . . . require[s] highly persuasive evidentiary support." *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)). These two principles require this Court to walk a "fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998).

Third, the prosecution history, though "often lack[ing] the clarity of the specification," may also be considered. *See Phillips*, 415 F.3d at 1317. This exchange between the patent examiner and the inventors was "created by the patentee in attempting to explain and obtain the patent," and may "demonstrat[e] how the inventor understood the invention." *Id.*

Lastly, this Court may also consider extrinsic evidence, such as expert testimony. This is because the patent claims and the specification are directed to those skilled in the relevant art—and therefore, a skilled artisan's view on the meaning of certain claim terms is relevant to what the claims mean. *See, e.g.*, *Phillips*, 415 F.3d at 1313 (quoting *In re Nelson*, 280 F.2d 172 (C.C.P.A. 1960), for the proposition that "[t]he descriptions in patents are not addressed to the public generally, to lawyers

or to judges, but, as section 112 says, to those skilled in the art to which the invention pertains or to which it was most nearly connected"). Thus, expert testimony may be considered in construing the claims so long as it stays true to the intrinsic evidence. *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1302 (Fed. Cir. 2005) ("Extrinsic evidence, such as expert testimony, may be useful in claim construction, but it should be considered in the context of the intrinsic evidence."); *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998).

One claim term at issue in this litigation is in "means-plus-function" format. *See* 35 U.S.C. § 112, ¶ 6 (2006). By statute, this claim term covers both any structure(s) in the specification and equivalents of that/those structures. *Id.* Construction of a "means-plus-function" term "requires identification of the function recited in the claim and a determination of what structures have been disclosed in the specification that correspond to the means for performing" the claimed function. *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1032 (Fed. Cir. 2002). Those structures that are clearly linked by the specification to the function are the structures that are literally within the scope of the claim—as are their equivalents. *Kahn v. Gen. Motors Corp.*, 136 F.3d 1472, 1476 (Fed. Cir. 1998).

IV. CONSTRUCTION OF '813 PATENT TERMS[3]

The '813 patent relates to an instrument comprising a concentric arrangement of an inner spatial volume and an outer spatial volume defined by an inflatable chamber, disposed near the distal end of a catheter body. One of the volumes contains a source of radiation, while the other volume may contain a radiation absorptive material. In one preferred embodiment, shown in Figure 1 of the patent, the inner volume is defined by an enclosed chamber surrounding the catheter body and containing a radioactive source. The outer chamber, surrounding the inner volume, is then inflated with air or other radiation absorbing material so that its wall contacts the wall of the surgical cavity substantially at all points. The distance between the radiation source and the wall of the outer chamber can be made

[3] Hologic addresses herein only those terms about which the parties disagree and which Hologic believes to be material to the resolution of this suit. As to terms not addressed, Hologic's position is as set forth in the parties' Joint Claim Construction Statement (to be filed on May 30, 2008, concurrently with parties' Reply Briefs), which Hologic incorporates by reference herein.

substantially constant. This embodiment permits the controlled delivery of radiation to a layer of tissue surrounding the surgical cavity.[4] By manipulating the volume and type of material in the outer chamber, the ratio of the absorbed dose at the surface of the wall of tissue to the dose at the tissue depth where the minimum dose is prescribed to be received can be controlled so as to maximize the efficacy of the treatment and minimize adverse side effects, namely, unwanted necrosis of healthy tissue.

The '813 patent teaches that other embodiments can be used to deliver therapeutic radiation to the layer of tissue surrounding a surgical cavity. Col 2:64 – 4:20; FIGS. 3-5. These other embodiments include the use of: (1) a radioactive liquid within an inner inflatable chamber; (2) a number of radioactive solid particles; (3) a slurry containing particles of a radioactive isotope; or (4) a solid radioactive source. Alternatively, these same radiation sources can be placed in the volume of space between the inner chamber and the outer inflatable chamber. Any of these embodiments might be used as a means of delivering radiation to tissue within the wall of a surgical cavity.

A. "inner spatial volume" (All Asserted Claims)

Hologic's Proposed Construction	SenoRx's Proposed Construction
a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide	A region of space surrounded by an outer spatial volume that is either enclosed by a distensible polymeric film wall or defined by the outside surface of a solid radionuclide sphere

There are two substantive differences between the proposed constructions. First, where the inner region of space is surrounded by a polymeric film wall, SenoRx seeks to add a requirement that the wall be "distensible." Secondly, SenoRx seeks to require that if the inner spatial volume is a radionuclide, that radionuclide must be a sphere. Both of SenoRx's additions to the claim language should be rejected.

SenoRx's argument that the claim should be limited to a "distensible polymeric film wall" is

[4] The tissue to be treated and the resected cavity can be thought of as an orange peel with the fruit (*i.e.,* the tumor) removed. A radiation source is placed within the space previously occupied by the fruit. The thickness of the "orange peel" corresponds to the thickness of the tissue to be treated – in most procedures the "orange peel" of tissue to be treated is about 2 centimeters thick. *See, e.g.,* '813 patent at FIG. 4.

incorrect. None of the claims refers to a distensible wall. In fact, during prosecution, claims directed to an embodiment including "an inner closed distensible chamber" were broadened—by deleting the word "distensible." Ex. I at 1, 2. "[I]t would be improper to disregard the effect of that action on the scope of those claims." *Libel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004). Nor does the specification require that the wall be distensible. Indeed, the "Summary of the Invention" section of the '813 patent, while referring to the "polymeric film wall" does not describe it as "distensible;" a pattern that is repeated elsewhere in the specification. *See* col. 1:50-55; col. 2:34-36, 56-58. Although established law prohibits a court from limiting the claimed invention to "preferred embodiments or specific examples in the specification," SenoRx attempts to do exactly that. *See Varco, L.P. v. Pason Sysytems USA Corp.,* 436 F.3d 1368, 1375 (Fed. Cir. 2006). There is no justification for reading the claims so narrowly, as this Court has already recognized. Ex. F at 3-5, 28 (April 27, 2007 Claim Construction Order in *Xoft, Inc. v. Cytyc Corp. et al*., Case No. C-05-05312 RMW [Dkt. No. 109].)

SenoRx's second attempt to limit the "inner spatial volume," by requiring a "spherical" radionuclide, is not supported by the intrinsic evidence.[5] The specification provides that "it is not essential that the chambers 30 and 34 have spherical walls . . . ." Col. 3:9-10*; see also.* col. 4:25-30 ("the invention can be carried out by . . . different equipment and devices . . . various modifications . . . can be accomplished without departing from the scope of the invention."). Claim 13 further shows that the applicants knew how to insert a spherical limitation when desired, but specifically chose not to do so with respect to claim 1.[6] *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 807 (Fed. Cir. 2007) ("The intrinsic evidence . . . suggests that the patentees knew how to restrict their claim coverage . . . .

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[5] The Court previously construed "inner spatial volume" to include either a polymeric film wall or a solid radionuclide *sphere,* adopting the sphericity language suggested in Xoft's proposed construction without analysis or comment. The main issue in the Xoft litigation was not the shape of the radionuclide, but whether Xoft's brachytherapy device used *any* radionuclide. Thus, the shape of the radionuclide was a tangential, non-briefed issue. Given the lack of intrinsic evidence for this limitation, Hologic respectfully advocates that such a limitation is unmerited despite being subsumed within the Court's prior construction of "inner spatial volume."

[6] Claim 13 reads "The apparatus as in claim 2 wherein the inner and outer chambers are spherical in shape and are concentric."

They could have used the word "[spherical]," as they did [elsewhere]. Instead, they chose a different term that implies a broader scope."). Moreover, one of ordinary skill in the art would appreciate that claiming a "spherical" radionuclide would not reflect the realities of standard brachytherapy practice, as solid radionuclides "generally available as brachytherapy radiation sources" at the time of the invention were and are not necessarily spherical. Col. 4:9-11; Verhey Decl. at 3-4.

B. "predetermined constant spacing between said inner spatial volume and the radiation transparent wall" (All Asserted Claims)

Hologic's Proposed Construction	SenoRx's Proposed Construction
spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical	Fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (*i.e.*, the inner spatial volume and outer chamber are concentric and the same shape)

The Court has already considered this claim term and agreed with Hologic's proposed construction. Ex. F at 6-7. In attempting to add "fixed spacing" and "each point on the wall or edge" limitations, among others, SenoRx offers no justification to modify the previous construction and lacks the intrinsic evidence to support its unduly restrictive interpretation. This claim term means that the spacing between the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, can be made constant. Ex. H at Ex. C (at 7:2-5). If the outer chamber is spherical, then the distance is constant in all directions. *Id*. If cylindrical, however, then the distance is constant around a radial plane that is perpendicular to the axis of the catheter. *Id*. Figures 1 and 3 (below, left and right, respectively) show the constant spacing between the inner spatial volume and the radiation transparent wall in both the spherical and ellipsoidal configurations.

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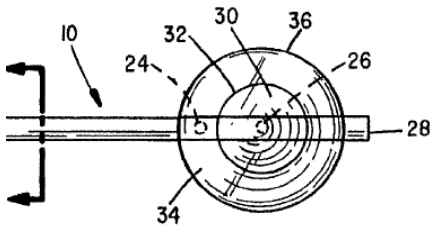

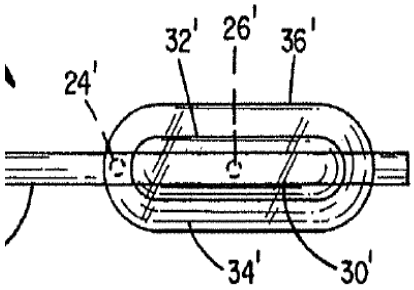

Rather than elucidate, SenoRx's addition of a "fixed spacing" limitation renders the claim more ambiguous. The word "fixed" has been cut by SenoRx from whole cloth; it does not appear anywhere in the intrinsic record. SenoRx's attempt to limit "constant" to "fixed" conflicts with the specification's explanation that "constant" should not be construed too literally—*i.e.*, the objective is to keep the spacing between the inner and outer chambers "somewhat," "substantially" or "generally" constant to avoid hot spots. Col. 4:15-16; 1:55-57; 3:11-13. Moreover, it is well understood that one skilled in the art may want to change the spacing during treatment, but as long as the spacing is "constant," this limitation is satisfied.

SenoRx also improperly seeks to require that "each point on the wall or edge of the inner spatial volume" be equidistant to "the closest point on the outer chamber." This construction improperly excludes a preferred embodiment of the invention (*see, e.g.,* FIG. 3 above[7]). The claims generically cover both spherical and non-spherical embodiments. And the written description further supports this conclusion by referring to both the spherical and non-spherical embodiments as including the claimed "constant spacing." *See* col. 3:10-13 (describing shape as secondary to a "generally constant spacing"). The claims should be construed accordingly. *Oatey Co. v. IPS Corp.,* 514 F.3d 1271, 1277 (Fed. Cir. 2008) ("At least where claims can reasonably to interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence on the contrary."). SenoRx's proposed additions to the Court's prior construction of this term should be rejected.

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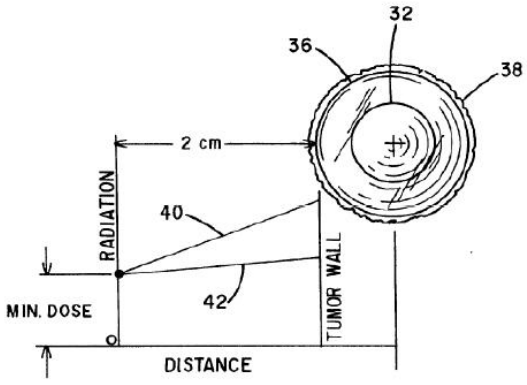
[7] In which the distance from the "wall or edge" of the inner spatial volume to the "closing point on the outer chamber" may not be the same at each end of the inner spatial volume.

C. "means…for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides" (All Asserted Claims)

Hologic's Proposed Construction	SenoRx's Proposed Construction
function: making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument structure: a radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents	Function: Making the absorbed dose of radiation substantially more uniform between the surface of the outer chamber and a predetermined depth in the target tissue. Structure: A radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, barium sulfate, or their equivalents, that performs this function by absorbing or attenuating radiation

The Court has already considered this limitation and agreed with Hologic's proposed construction. Ex. F at 8-10. For the same reasons set forth in the Court's Claim Construction Order, the Court should adopt Hologic's construction.

The first step in the construction of this means-plus-function element is a determination of the claimed function. *JVW Enters.*, 424 F.3d at 1330. Here, the function identified by the limitation is "rendering uniform the radial absorbed dose profile of the emissions . . . ." Col. 4:49-50. As Dr. Verhey explains, the radial absorbed dose profile is the absorbed dose in tissue, which varies as a function of distance from the center of the cavity along a direction of interest. Ex. H at Ex. C (at 6:21-28). In the '813 patent, the direction of interest would be from the cavity wall to a specific depth in the target tissue at which a prescribed therapeutic dose is defined. *Id*. The specification explains that one goal of the invention was to render the absorbed dose profile in the target tissue more uniform than it would otherwise be - thereby "preventing over-treatment of body tissue at or close to the outer wall 36 of the instrument." Col. 3:28-33. Describing Figure 4 (shown left), the written description explains the objective of flattening line 40 to achieve an absorbed dose profile depicted by line 42. *See* Col. 4:14-38.



The specification does not provide any basis for requiring a "substantial" change in the absorbed dose profiles. Rather, it describes a more "uniform" profile. *See* Abstract ("the apparatus functioning to provide a *more uniform* absorbed dose profile . . ."); Col. 1:63-67 ("so as to provide a *more radially uniform* radiation dosage"); Col. 1, line 36 ("as uniform as possible"); *see also* Ex. F at 9 ("[T]he inventor's purpose was to deliver radiation more uniformly than had previously been done, thus preventing over-treatment of body tissue at or close to the outer wall . . . of the instrument.") In this context, "uniform" means uniform enough to serve the objects of the invention. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565-67 (Fed. Cir. 1992) ("lubricated" means sufficient lubricant to serve the invention's purpose); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc*. 796 F.2d 443 (Fed. Cir. 1986) (same). No intrinsic evidence champions a requirement that the radial absorbed dose be "*substantially*" more uniform.

The second step in construing this means-plus-function element is an identification of the corresponding structure in the written description. *JVW Enters.*, 424 F.3d at 1330; 35 U.S.C. § 112, ¶ 6. The parties agree that the corresponding structure disclosed in the specification is "a radiation absorbing or attenuating material," but SenoRx attempts to add the words "*that performs this function by absorbing or attenuating radiation*." SenoRx seeks to interject additional function to the claim under the guise of calling it "structure." This, of course, is impermissible. *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1334 (Fed. Cir. 2006) ("A court errs when it improperly imports unclaimed functions into a means-plus-function claim limitation."). Because this language does not describe any structure at all, but rather seeks to impose additional, unclaimed function into the claim, it should be rejected.

D. "inner, closed chamber" (Asserted Claim 11)[8]

Hologic's Proposed Construction	SenoRx's Proposed Construction
inner, closed chamber	A compartment located completely inside of the outer chamber and closed off within the outer chamber

[8] This element is contained within Claim 2 on which asserted Claim 11 depends (via Claim 8).

The term "inner, closed chamber" should be construed to mean exactly that, an "inner, closed chamber." *See U.S. Surgical Corp. v. Ethicon, Inc.* 103 F.3d 1554, 1568 (Fed. Cir. 1997) (holding that courts are not required to construe every disputed term unless necessary). This term has an ordinary and customary meaning to one of skill in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. Thus, "inner, closed chamber" should be construed to mean "inner, closed chamber."

SenoRx's proposed construction cannot be correct because it would exclude a preferred embodiment. *See* '813 patent, FIG. 1 & Col. 2:35-37 (describing and depicting an inner "chamber 30 [that] is in fluid communication with the inflation port 26," thus the inner spatial volume is not "completely" inside the outer chamber and not "closed off within the outer chamber."); *Oatey,* 514 F.3d at 1276-77 (a claim interpretation excluding a preferred embodiment is "rarely, if ever, correct"). Indeed, SenoRx's agreement that "outer, closed, inflatable chamber" (in asserted claim 1 of the '813 patent) is unambiguous and requires no additional construction belies its contention that the similar term "inner, closed chamber" is unclear and requires construction.

Further, the Court already considered and rejected an analogous argument (made with respect to the related '204 patent) in the context of Hologic's Motion for Preliminary Injunction. Ex. F at 7:15-8:10. SenoRx argued that the lumens in its Contura device protrude into the catheter shaft and therefore cannot constitute an "inner spatial volume" because they are not completely surrounded by the outer spatial volume. *Id.* The Court disagreed, reasoning that if SenoRx were correct, that construction would impermissibly exclude the embodiments wherein the portion of the device holding the radioactive material in the inner spatial volume was in contact with the outer spatial volume. *Id.* at 7:22-8:10. The same reasoning applies to the term "inner, closed chamber" in the related '813 patent, which has essentially the same disclosure as the '204 patent. *See* Ex. A at FIGs. 1, 3 and 5, col. 2:35-42. Thus, to adopt SenoRx's proposed construction of "inner, closed chamber" would impermissibly exclude a preferred embodiment from the claims.

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E. "plurality of radioactive solid particles" (Asserted Claim 12)

Hologic's Proposed Construction	SenoRx's Proposed Construction
plurality of radioactive solid particles	two or more separate radioactive solid particles placed in the inner spatial volume at the same time

This term means what it says - a "plurality of radioactive solid particles." *See Ethicon, Inc.* 103 F.3d at 1568. There was no attempt by the inventors to impart a novel or special meaning to this term and there is no need to further refine the language they chose to define their invention. Furthermore, this Court has already considered the meaning of this term within the context of the '813 patent and found that no further clarification of the meaning is appropriate. Ex. F at 11-12, 28. Thus, "plurality of radioactive solid particles" should be construed to mean "plurality of radioactive solid particles." There is no need to clarify that "plurality" means "two or more" or that the particles have to be "separate."

In any event, no intrinsic evidence supports SenoRx's contention that the "plurality of radioactive solid particles" in claim 12 must be "placed in the inner spatial volume *at the same time*." Claim 12 simply refers to the solid particles having pre-determined locations. Col. 6:1-5. Neither the specification nor the prosecution history suggests that the particles must be placed in the inner volume at the same time. Col. 2:69-3:9; Fig. 5.

F. "predetermined locations" (Asserted Claim 12)

Hologic's Proposed Construction	SenoRx's Proposed Construction
predetermined locations	more than one predetermined location

Hologic agrees with SenoRx's proposed construction. Thus, "predetermined locations" should be construed to mean "predetermined locations." No further construction of this term is necessary.

G. "plurality of radioactive solid particles placed at predetermined locations" (Asserted Claim 12)

Hologic's Proposed Construction	SenoRx's Proposed Construction
plurality of radioactive solid particles placed at predetermined locations	two or more separate radioactive solid particles placed in the inner spatial volume at the same time at more than one predetermined location

Again, the limitation means what it says, making further elaboration on its meaning unnecessary. *See Ethicon,* 103 F.3d at 1568. This term has an ordinary and customary meaning to one of skill in the art, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. Furthermore, this Court has already considered the meaning of this term within the context of the '813 patent and found that no further clarification of the meaning is appropriate. Ex. F at 11-12, 28 ("[S]ince the language is understandable as is, no construction of [this claim term] is necessary or appropriate."). Thus, "plurality of radioactive solid particles placed at pre-determined locations" should be construed to mean "plurality of radioactive solid particles placed at predetermined locations."

In any event, there is no basis for SenoRx's narrow claim interpretation. Again, there is no intrinsic basis for adding a restriction that multiple, *separate,* solid particles be placed in the inner spatial volume *at the same time*. Neither the specification, the prosecution history, nor Claim 12 imposes such a limitation on the unambiguous language of the claim. Col. 6:1-5; Col. 2:69-3:9; Fig. 5.

V. CONSTRUCTION OF '204 PATENT TERMS

The '204 patent is a continuation-in-part of the '813 patent. The asserted claims are directed toward an apparatus for brachytherapy used to irradiate interstitially diseased cells within the tissue surrounding the cavity created by the surgical removal of proliferative (e.g., cancerous) tissue. The apparatus includes a catheter body member having a proximal end and a distal end, an inner spatial volume proximate to the distal end of the catheter body member, an outer spatial volume defined by an expandable surface element proximate to the distal end of the body member, and surrounding and concentric with the inner spatial volume. In a preferred embodiment, a radiation source is disposed within the inner spatial volume.

The '204 patent describes a number of different sources of radioactivity that can be used to deliver the therapeutic radiation to the excision cavity, including, without limitation, radioactive microspheres (FIG. 4), concentric non-spherical chambers (FIG. 5), a single, solid radiation emitting material surrounded by an expandable cage defining the shape of the tumor cavity (FIG. 6), a radioactive fluid filling the inner chamber and the outer chamber filled with air or other radiation

absorbing substance (FIG. 7b), and a single, solid source surrounded by an outer chamber filled with a radiation absorbing substance (FIG. 7c). Figure 7d shows examples of radiation profiles which might be obtained by the embodiments shown in Fig. 7a-7c where the depth of interest is shown as 2 cm from the surface of the outer volume. As can be seen, different embodiments can be used to vary the ratio of the dose at the prescribed depth to the dose at the wall of the cavity.

A. "inner spatial volume" (All Asserted Claims)

Hologic's Proposed Construction	SenoRx's Proposed Construction
a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide.	A region of space surrounded by an outer spatial volume that is either enclosed by a distensible polymeric film wall or defined by the outside surface of a solid radionuclide sphere

Constructions proposed by both parties consider the phrase "inner spatial volume" within the parent '813 to be the same within the child '204 patent. Because the '813 and '204 patents are related, this claim term should carry the same construed meaning in both patents. *See Omega Eng'g, Inc. v. Raytek Corp*., 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning."); *PCTEL, Inc. v. Agere Sys., Inc.*, 2005 WL 2206683, at *3 (N.D. Cal., Sept. 8 2005) ("[w]here patents-in-suit share the same disclosures, common terms are construed consistently across all claims in both patents"). Thus, as explained above in section IV.A, "inner spatial volume" should be construed to mean "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide."[9]

B. "outer spatial volume" (All Asserted Claims)

The parties have agreed to adopt the construction "a region of space defined by an expandable surface element and surrounding an inner spatial volume." No further construction of this term is

[9] In addition to the reasons already given for interpreting "inner spatial volume" as Hologic proposes, claim 9 of the '204 patent states that "the inner spatial volume is an inner closed, distensible chamber," suggesting that claims that do not include the "distensible" element are not so limited. *See Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (claim differentiation creates a "presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim.").

necessary.

C. "providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface" (Asserted Claim 4)[10]

Hologic's Proposed Construction	SenoRx's Proposed Construction
controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target tissue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface	Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target tissue so as to reduce or eliminate the risk of damage to healthy tissue in contact with the expandable surface as compared to devices in which the tissue is directly adjacent to the radiation source

The Court has already considered this limitation and agreed with Hologic's proposed construction. Ex. F at 23. The '204 specification clearly explains that the various embodiments of the apparatus work to control the ratio of the dose at the surface of the outer spatial volume to the dose at the prescription depth, thereby reducing or preventing necrosis proximate the expandable surface. Col. 1:55-60, 2:7-18, 51-55.; 6:52-60. SenoRx's proposed language "so as to reduce or eliminate the risk of damage" is inconsistent with one of the purposes of the invention. One of the inventor's express objectives was to reduce or eliminate necrosis—not to reduce or eliminate "risk." *Id*. Similarly, the applicant sought to prevent healthy cells from dying (*i.e.*, "necrosis")—not merely from being sub-lethally "damaged." *Id*. Hologic's proposed construction more accurately reflects the invention's stated purpose—and the language of the claim. *See Phillips*, 415 F.3d at 1316 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.").

There is also no basis for adding a limitation that the '204 patent invention provide a controlled dose of radiation that improves upon "devices in which the tissue is directly adjacent to the radiation source." The claimed invention discloses a better way to perform brachytherapy, but is not limited to an improvement over unspecified prior art devices. SenoRx's argument lacks adequate support in the

[10] This element is contained within Claim 2 on which asserted Claim 4 depends.

language of the claim - or, for that matter, elsewhere in the intrinsic record. This absence of support undermines any justification for construing this term in a way that would limit the invention to an improvement over a particular prior art technique.

D. "predetermined spacing…between said inner spatial volume and the expandable surface element" (Asserted Claim 4)[11]

Hologic's Proposed Construction	SenoRx's Proposed Construction
the distance between the inner spatial volume and the expandable surface element is determined in advance	Fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the wall of the expandable surface element, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the expandable surface element is the same (*i.e.*, the inner spatial volume and expandable surface element are concentric and the same shape)

This term is similar to the term "predetermined constant spacing between said inner spatial volume and the radiation transparent wall," discussed above in Section IV.B. However, in some respects, this term is broader. First, it does not require "constant" spacing. Second, rather than claiming a "radiation transparent wall," the claim calls for an "expandable surface element." Hologic contends that this "predetermined spacing" is "the distance between the inner spatial volume and the expandable surface element" and that the spacing "is determined in advance."

As it did with respect to the '813 patent, SenoRx again attempts to read limitations into the claim that are not supported by the claim language itself,the written description or the prosecution history. Because the '204 and '813 patents share similar disclosures, Hologic incorporates its arguments set forth in Section IV.B and requests that the Court reject SenoRx's unduly restrictive reading of this term.

F. "plurality of solid radiation sources" (Asserted Claim 17)

Hologic's Proposed Construction	SenoRx's Proposed Construction
plurality of solid radiation sources	Two or more separate radioactive solid sources placed in the inner spatial volume at the same time

[11] This element is contained within claim 3 on which asserted claim 4 depends.

The phrase "plurality of solid radiation sources" in the '204 patent mirrors the nearly identical phrase "plurality of radioactive solid particles" in the parent '813 patent. SenoRx proffers an identical construction for each, and no elaboration on the meaning of either term is necessary. *Ethicon,* 103 F.3d at 1568; Ex. H at 4. Because the '813 and '204 patents are related, this claim term should carry the same construed meaning as the nearly identical terms in the '813 and '204 patents. *See Omega Eng'g, Inc.*, 334 F.3d at 1334; *PCTEL, Inc.*, 2005 WL 2206683, at *3. Thus, "plurality of solid radiation sources" should be construed to mean "plurality of solid radiation sources."

F. "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element" (All Asserted Claims)[12]

Hologic's Proposed Construction	SenoRx's Proposed Construction
three-dimensional isodose profile that is substantially similar in shape to the expandable surface element	a final three-dimensional isodose profile that is substantially similar in shape to the outer spatial volume expandable surface and is concentric with the outer spatial volume expandable surface

This claim term means what it says and that no further elaboration is necessary. *Ethicon,* 103 F.3d at 1568. This term has an ordinary and customary meaning to one of skill in the art. Moreover, there is no evidence that the inventors intended to impart a novel or special meaning to the term. Thus, "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element" should be construed to mean "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element."

SenoRx's proposed construction fabricates new restrictions on otherwise clear claim language without any support in the intrinsic record. Because SenoRx's approach is contrary to established claim construction principles, it should be rejected. First, SenoRx's proposes adding the word "final" to describe the isodose profile, which serves only to create ambiguity where none exists. The claim language makes no reference to any temporal standard, so there is no baseline against which to evaluate "final." Second, referring to a "final" isodose profile suggests that use of the apparatus

[12] This element is contained within Claim 1 on which both asserted claims depend.

generates multiple, "intermediate," isodose profiles, and that only the "final" one is substantially similar in shape to the expandable surface element. No intrinsic evidence supports this conclusion or provides justification for adding such a limitation.

Again, with the language "concentric with the outer spatial volume expandable surface," SenoRx manufactures a claim limitation where none exists. This is not an attempt to clarify the "substantially similar" claim language—SenoRx retains that language, but then seeks to impose a requirement that the profile be "concentric." The claims do not require this. *Phillips*, 415 F.3d at 1313 (the words of the claims define the subject matter that the inventors intended to claim). Likewise, neither the written description nor the prosecution history suggests that the claim language be so limited. SenoRx's proposed construction should be rejected.

G. "isodose profile having a shape substantially similar to the shape of the outer spatial volume" (Claim 17)

Hologic's Proposed Construction	SenoRx's Proposed Construction
isodose profile having a shape substantially similar to the shape of the outer spatial volume	a final three-dimensional isodose profile that is substantially similar to the shape of the outer spatial volume expandable surface and is concentric with the outer spatial volume expandable surface

This claim term means what it says and that further elaboration of that meaning is unnecessary. *See Ethicon, Inc.* 103 F.3d at 1568. One of ordinary skill in the art would understand the meaning of this claim term without altering the claim language. Ex. H at 4. Thus, "isodose profile having a shape substantially similar to the shape of the outer spatial volume" should be construed to mean "isodose profile having a shape substantially similar to the shape of the outer spatial volume."

SenoRx's proposed construction is identical to its definition of the similar phrase within claim 1 ("three-dimensional isodose profile that is substantially similar in shape to the expandable surface element") discussed immediately above. *See, supra,* at section V.F. As discussed in section V. F. above, SenoRx's proposal, rather than clarifying the language at issue, creates ambiguity and adds unsupported limitations to the claim term. SenoRx's proposed construction should be rejected. *MBO Labs.,* 474 F.3d 1323 at 1333; *JVW Enters.*, 424 F.3d at 1335.

VI. CONSTRUCTION OF '142 PATENT TERMS

The '142 patent, a continuation-in-part of both the '813 and '204 patents, describes an apparatus that delivers localized radiation in an asymmetric fashion to target tissue surrounding a surgical extraction site. The apparatus includes an expandable outer surface element defining an apparatus spatial volume, a radiation source disposed within the apparatus volume, and a means for providing a predetermined asymmetric isodose profile within the target tissue. Several embodiments include a radiation source shaped or located so as to be asymmetrically placed with respect to the longitudinal axis of the apparatus to create asymmetric isodose curves within the target tissue. *See, e.g.,* FIGS. 1, 3-7. In particular, FIG. 4 illustrates an embodiment in which three curved radiation source wires, each including a number of solid radiation particles, are arranged asymmetrically with respect to the longitudinal axis of the device to achieve the desired asymmetric isodose profiles.

A. "located so as to be spaced apart from the apparatus volume" (Claim 1)

Hologic's Proposed Construction	SenoRx's Proposed Construction
located so as to be not on or touching the apparatus volume	located outside (*i.e.*, not within) the apparatus volume

The proper construction of the phrase "located so as to be spaced apart from the apparatus volume" is one in which the claim term is not read in isolation, "but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. Both within the specification and during prosecution, the '142 inventors made clear that "spaced apart" referred to the positional relationship between the radiation source and the wall of the expandable outer surface element, and hence the target tissue. Col. 4:27-30 (an "outer spatial volume 30" is "affixed to the tubular body 12"). This outer spatial volume is "defined by an outer polymeric film barrier 32 that is appropriately *spaced from the radioactive source*." Col. 4:27-30. Indeed, the inventors distinguished the prior art on the basis that

> [T]he radiation source is disposed completely within the expandable surface and spaced apart from the apparatus volume. (*See* Page 8, line 23 to page 9 line 13, noting the advantages of providing the radiation source within the interstitial volume and spaced apart from the target tissue . . .).

Ex. J at 6-7. The inventors further stated that "the radiation source is arranged within the device so

that asymmetric dosing appears *at the apparatus volume*," indicating that the apparatus volume is located adjacent to the band of tissue to be treated, and is not intended to be a geometric volume of space encapsulated by the expandable outer surface. *Id.* at 7 (Response to Office Action); *see also id.* at 8 (comparing the balloon disclosed in the Apple reference to the "apparatus volume" of claim 1). In short, SenoRx's proposed construction would do what is virtually never proper: exclude all disclosed embodiments of the patent. SenoRx cannot present the "highly persuasive evidentiary support" necessary to do so.[13] *Vitronics*, 90 F.3d at 1583.

As recognized by both this Court and Dr. Verhey, "a common sense reading indicates that one of skill in the art could understand the claim to mean that the radiation source must be inside and spaced apart from the surface of the expandable outer surface." Ex. E at 16; Ex. H at 5-6. SenoRx's proposed construction should be rejected as contrary to the language of both the specification and prosecution history.

B. "being provided on at least two elongate members extending into the apparatus volume" (Claim 6)

Hologic's Proposed Construction	SenoRx's Proposed Construction
being provided on at least two elongate members extending into the apparatus volume	radiation sources are attached to two or more elongate members (e.g., wires or rods) that extend into the three-dimensional region of space within the expandable outer surface at the same time

One of ordinary skill in the art would understand the meaning of this claim term. . Nothing in the intrinsic record demonstrates that the inventors attempted to impart a novel interpretation to this

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[13] SenoRx has relied heavily on Cytyc's construction of "inner spatial volume" from the *Xoft* case. Although the '142 patent is a continuation-in-part of the '813 patent at issue in *Xoft*, the terms "apparatus volume" and "inner spatial volume" are quite different and served different purposes. Moreover, the relevant specification and prosecution history are distinct with respect to the term "apparatus volume" and "spaced apart from the apparatus volume." The construction of "inner spatial volume" from the '813 patent is thus irrelevant to the construction of "apparatus volume" in the '142 patent. Indeed, the claims in a continuation-in-part may have different meanings than in their parent patents. *See, e.g.*, *Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc.*, 248 F.3d 1303, 1315 (Fed. Cir. 2001) (refusing to use intrinsic evidence from parent application pertaining to a claim term different than the term under consideration); *cf. Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (citing *Jonsson v. The Stanley Works,* 903 F.2d 812, 817-818 (Fed.Cir.1990), for the proposition that "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents *that contain the same claim limitation*" (emphasis added)).

language. Therefore, it should be construed to mean what it says. Thus, "being provided on at least two elongate members extending into the apparatus volume" should be construed to mean "being provided on at least two elongate members extending into the apparatus volume."

SenoRx's arguments should be rejected. SenoRx impermissibly adds the limitation that two or more elongate members extend "at the same time." *MBO Labs.,* 474 F.3d at 1333. Nothing in the patent validates this proposed additional limitation. To the contrary, the specification contemplates removing the radionuclide during treatment, noting that

> it is desirable to provide an interstitial brachytherapy device configured to provide a dose in a therapeutic range, say between 40 to 60 Gray, at a distance between 0.5 and 1.0 cm from the outer spatial volume for an outer spatial volume having a diameter of 4.0 cm and being in contact with the resection cavity wall. In a typical embodiment, the radioactive source material ranges from approximately 150 to 450 mCi in activity and encompasses most of the target treatment area with a 0.4 to 0.6 Gray/hour isodose contour. At this treatment rate, treatment may be completed in approximately 3 to 7 days, or more commonly, in approximately 3 to 5 days.

Col. 5:66 –6:10. To deliver a dose of 40 Gray at a rate of 0.6 Gray/hour, for example, would entail almost 67 hours of treatment with a radionuclide, which treatment the patent instructs can be completed over 3 to 7 days rather than continuously for the full 67 hours. *Id*. The patent further teaches that the radioactive source material may be removed before the apparatus is removed. Col. 3:47-52. Thus, the patentees considered the temporal issues associated with radiation treatment using their device, but chose not to limit the claims to any one temporal embodiment. To do so now violates the Federal Circuit's proscription against importing new limitations into claims.

C. "at least one of the elongate members being shaped to provide asymmetric placement of the radiation source with respect to a longitudinal axis through the apparatus volume" (Claim 6)

Hologic's Proposed Construction	SenoRx's Proposed Construction
At least one elongate member is shaped so as to place the radiation source not on the longitudinal axis through the apparatus volume	at least one elongate member (e.g., a wire or rod) is shaped so that a radioactive source attached to that member is not located on the longitudinal axis of the device

The parties agree to SenoRx's proposed construction of this term as meaning "at least one elongate member (e.g., a wire or rod) is shaped so that a radioactive source attached to that member is

not located on the longitudinal axis of the device." No further construction of this term is necessary at this time.

D. "apparatus volume" (Claims 1 & 6)

Hologic's Proposed Construction	SenoRx's Proposed Construction
apparatus volume	The three-dimensional region of space within the expandable outer surface

Hologic addresses the construction of "apparatus volume" in the context of surrounding claim language, *i.e.*, within the phrase "three-dimensional apparatus volume configured to fill an interstitial void" (discussed immediately below), and a separate construction of this term divorced from the context of the surrounding claim language is neither required nor appropriate. *See Phillips*, 415 F. 3d at 1314.

E. "three-dimensional apparatus volume configured to fill an interstitial void" (Claims 1 & 8)

Hologic's Proposed Construction	SenoRx's Proposed Construction
A three-dimensional geometric solid composed of an expandable outer surface	The three-dimensional region of space within the expandable outer surface

Read in light of the intrinsic record, there is only one reasonable meaning of "apparatus volume": "a three-dimensional geometric solid composed of an expandable outer surface."[14] By way of illustration, the specification describes an "outer spatial volume" that is "defined by an outer polymeric film barrier 32 that is appropriately ***spaced*** from the radioactive source." Col. 4:27-30; Ex. E at 15. The '142 inventors relied upon this understanding during prosecution before the PTO. *See, supra* at section VI.A. Dr. Verhey also testified that one of ordinary skill in the art would recognize that the apparatus volume must be defined as by Hologic. Ex. H at 4-5. Moreover, the Court has already found, in ruling on Hologic's Motion for Preliminary Injunction, that common sense dictates the apparatus volume cannot be a region of space within the expandable outer surface. Ex. E at 16. SenoRx's construction is possible only if one disregards the context of the claim term and improperly

[14] By way of analogy, the skin of a basketball defines a three-dimensional basketball.

reads the claim language in a vacuum, which is improper. *Phillips*, 415 F.3d at 1313.

F. "asymmetrically located and arranged within the expandable surface" (Claim 1)

Hologic's Proposed Construction	SenoRx's Proposed Construction
Located and arranged so as not to be on the longitudinal axis of the expandable surface	Located and arranged inside the expandable surface so as not to be concentric with the expandable outer surface

Hologic advances a construction that harmonizes the plain language of the claim with the explicit disclosures within the specification. The '142 patent unequivocally calls out the benchmark against which asymmetry of the radiation source is measured: the longitudinal axis of the apparatus. Col. 2:65-3:1 (" …locating the radiation source so as to be asymmetrically placed with respect to a longitudinal axis of the apparatus"); Col. 5:12-13 ("Radiation source 24 has an asymmetric configuration with respect to a longitudinal axis of the instrument 10."). Every teaching of asymmetry within the '142 patent refers to the radiation source being offset from the longitudinal axis of the device. *Id.*; Col. 3:11-19; Col. 5:20-23; FIG. 4; Abstract. Even when a liquid radioisotope is used, the inner volume containing that isotope is "asymmetrically shaped or located with respect to the longitudinal axis"…and not the expandable outer surface. Col. 7:5-9. Hologic's proposed construction is consistent with both the plain meaning of the claim language and the written description.

SenoRx, in contrast, promotes a construction that is inconsistent with the patent's explicit teachings. In fact, SenoRx seeks to exclude preferred embodiments. For example, the '142 patent discloses embodiments in which a radioactive source is concentric with the expandable outer surface. Solid radiation particles 126 in FIG 6, 52 in FIG. 3, and unnumbered (attached to a wire along the longitudinal axis) in FIG 4, as well as liquid radiation source 108 in FIG. 5 each illustrate radiation sources concentric with the outer expandable surface of the device. The Court should reject SenoRx's construction because it would exclude those embodiments from the scope of the claim. *See Oatey,* 514 F.3d at 1277 ("At least where claims can reasonably to interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence on the contrary."); *NeoMagic Corp.*, 287 F.3d at 1074. Hologic's proposed constructions stay true to the

claim language and the intrinsic record and should be adopted.

G. "predetermined asymmetric isodose curves (All Asserted Claims)

Hologic's Proposed Construction	SenoRx's Proposed Construction
Predetermined isodose curves that are not symmetric with respect to the longitudinal axis of the apparatus volume	Isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume

Hologic's construction comports with both the intrinsic and extrinsic record. Ex. H at 6. The '142 patent repeatedly defines the asymmetry of the isodose profile relative to the longitudinal axis of the device. Col. 5:19-25 ("The asymmetrically shaped isodose curve 40 [in FIG. 1] may be created by providing a plurality of solid radioactive particles 36 on a curved wire 34 in a spaced apart relationship. This configuration will result in certain of the solid radioactive particles 36 being further from the longitudinal axis 38 of the instrument 10 than others, and will result in the illustrated asymmetric isodose profile 40."); Col. 5:14-18 (…radiation source 24 is shaped so as to result in an isodose profile 40 that varies radially about the longitudinal axis 38. More simply, the isodose profile 40 of FIG. 1 has a shorter radius from the longitudinal axis 38 on the top side of the instrument 10 as shown in FIG. 1 than on the bottom side."); Col. 3:1-6 ("In one example …an inner volume containing a liquid radioisotope is asymmetrically placed within the apparatus volume so as to result in an isodose profile in the target tissue that is asymmetric about the longitudinal axis of the apparatus.").

SenoRx's proposed construction is inconsistent with the definition of "asymmetric" provided in the specification. SenoRx would require that the isodose profile not be substantially the same shape as the apparatus volume, and/or not concentric with the apparatus volume. *MBO Labs,* 474 F.3d at 1333. The '142 patent teaches that "[i]n some applications, the desired dosing profile is consistent with the shape of the outer volume 30. That is, the absorbed dose within the target tissue at points equidistant from the surface 32 of the outer spatial volume 30 should be substantially uniform in substantially every direction." Col. 6:11-15. The specification's use of the phrase "in some applications" implies that there are other applications in which the dosing profile is ***not*** "consistent with the shape of the outer volume.

Moreover, SenoRx's view that the dosing profile cannot be concentric is unduly narrow – the intrinsic evidence defines "asymmetric" as being off-axis, not simply non-concentric (*i.e.*, relative to a central point). Thus, a dosing profile centered on the longitudinal axis but not concentric with the balloon – *i.e.*, as in the case of an off-center dwell position of a radionuclide in a central inner lumen – would not be included in the patent's definition of "asymmetric." SenoRx's construction is therefore incorrect.

H. "plurality of solid radiation sources" (Claim 6)

Hologic's Proposed Construction	SenoRx's Proposed Construction
plurality of solid radiation sources	Two or more separate radioactive solid sources placed within the expandable outer surface at the same time

This claim term means what it says. There is no evidence of any intent by the inventors to impart a novel or special meaning to the term, and those skilled in the art appreciate what is claimed based on the unambiguous claim language itself. Ex. H at 6. Thus, "plurality of solid radiation sources" should be construed to mean "plurality of solid radiation sources".

Once again, SenoRx attempts to add a temporal limitation ("*at the same time*") to the otherwise unambiguous claim language without support in the intrinsic record. Neither the specification nor the prosecution history suggests that the particles must be placed in the inner volume at the same time. *See* Col. 2:69-3:9; Fig. 5. In fact, the plain meaning of this element encompasses a single radioactive seed inserted into different lumens at different times. This Court should therefore decline SenoRx's invitation to read temporal limitations into this claim term where the claim language calls for none.

VII. CONCLUSION

Hologic's proposed constructions comport with the intrinsic and extrinsic evidence, as well as with the plain meaning of the terms under construction. In contrast, SenoRx's proposed constructions import several new claim limitations, and, in general, lack intrinsic support. For these reasons, plaintiffs respectfully requests that the Court adopt Hologic's proposed constructions.

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Dated: May 21, 2008

HOWREY LLP

By: /s/
Katharine L. Altemus

HOWREY LLP
Attorneys for Plaintiffs
Hologic, Inc., Cytyc Corporation,
and Hologic L.P.

PROOF OF SERVICE

I am employed in the County of San Mateo, State of California. I am over the age of 18 and not a party to the within action. My business address is 1950 University Avenue, 4th Floor, East Palo Alto, California 94303.

On May 21, 2008, I served on the interested parties in said action the within:

PLAINTIFFS' OPENING CL;AIM CONSTRUCTION BRIEF (PATENT L.R. 4-5(a)) and DECLARATION OF KATHARINE L. ALTEMUS IN SUPPORT OF PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF (PATENT L.R. 4-5(a)) with sealed Exhibits E and F

by placing a true copy thereof in a sealed envelope(s) addressed as stated below and causing such envelope(s) to be deposited in the U.S. Mail at East Palo Alto, California.

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I declare under penalty of perjury that I am employed in the office of a member of the bar of this Court at whose direction the service was made and that the foregoing is true and correct.

Executed on May 21, 2008, at East Palo Alto, California.

Sonya Schwab
(Type or print name)

Sonya Schwab
(Signature)